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### REMARKS

In view of the above amendment and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-20, the only claims pending and currently under examination in this application.

Claim 5 has been amended to replace the word "analyte" with the word "component", where the word "component" finds proper antecedent basis in Claim 1 from which it depends.

As no new matter has been added by the above amendment, the Applicants respectfully request entry thereof.

#### Oath/Declaration

The Office Action states that a new oath or declaration is required. Accordingly, the Applicants herewith submit a new declaration.

#### Rejection under 35 U.S.C. § 112, second paragraph

Claims 4-5, 9 and 15 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

In regards to Claims 4, 9 and 15, the Examiner states that it is unclear how the porosity of the micro-valve is modulated and states that it is though that the intent is to recite that the porosity of the phase reversible material is actually modulated.

The Applicants respectfully submit that the recitation that specifies modulating the porosity of a micro-valve is definite under 35 U.S.C. § 112, second paragraph. Specifically, since a micro-valve of the subject invention includes a phase reversible material and the porosity of the phase reversible material may be varied or modulated, the porosity of the micro-valve may be varied or modulated.

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The Applicant's direct the Examiner's attention to the specification, for example at page 7, lines 12-24:

As such, the phase reversible material is a material that is capable of going from a first stage that is substantially permeable to fluid, i.e., allows free flow of fluid, to a second stage that is substantially impermeable to fluid, i.e., substantially inhibits fluid flow. Specifically, the material is one that is capable of going from a first, porous state to a second, substantially non-porous state. Any phase reversible material may be employed, so long as the material changes in phase in response to an applied stimulus in a manner sufficient to modulate its fluid permeability, i.e., the ability of fluid to flow through the material. Put another way, the porosity of the phase reversible material varies in response to an applied stimulus, such that by applying various stimuli to the phase reversible material of the micro-valve, the porosity of the micro-valve and therefore its permeability to molecules of different molecular weight, may be varied or modulated, generally in a manner proportional to the applied stimulus and magnitude thereof.  
(Emphasis added.)

Accordingly, the Applicants submit that the porosity of the micro-valve may be modulated and thus this recitation does not render the Claims 4, 9 and 15 indefinite under 35 U.S.C. § 112, second paragraph. As such, the Applicants respectfully request that this rejection be withdrawn.

In regards to Claim 5, the Examiner states that there is insufficient basis for the term "said at least one analyte". As noted above Claim 5 has been amended to replace the word "analyte" with the word "component", where the word "component" finds proper antecedent basis in Claim 1 from which it depends. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

**REJECTION UNDER 35 U.S.C. §102(b)**

Claims 1-16 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Balch et al. (US 5,746,901).

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Under current case law, a reference does not anticipate a claim unless "all of the elements and limitations of the claim are found within [that]...reference...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention." Scripps Clinic v. Genentech, Inc., 18 USPQ2d 1671, 1672 (Fed. Cir. 1992).

Therefore, in order for a claim to be anticipated by a reference, each and every limitation must be found in that reference. The Applicants respectfully submit that each and every claimed limitation is not found in the cited reference.

For example, independent Claims 1, 6 and 12, and the claims that depend therefrom, specify methods wherein a multi-component fluidic sample is contacted with a micro-valve under conditions for at least one component to at least move into the micro-valve while the remaining components remain outside the micro-valve. In other words, in practicing the subject methods to at least move one component into the micro-valve, remaining components do not enter the micro-valve at all and instead remain outside of the micro-valve.

In contrast, Balch et al. do not teach a method that includes moving at least one component of a multi-component fluid sample into a micro-valve while the remaining components remain outside the micro-valve. Specifically, Balch et al. is directed to a hybrid slab-microchannel gel electrophoresis system that incorporates a microslab portion of the separation medium above the microchannels. However, nowhere in Balch et al. is a method taught that includes employing a micro-valve that is permissive to the entry of at least one component of a multi-component fluid sample while completely impennissive of other components of the fluid sample such that remaining components do not enter the micro-valve but instead remain outside the micro-valve. In other words, Balch et al. do not teach a method that includes moving at least one component of a multi-component fluid sample into a micro-valve while the remaining components remain outside the micro-valve. For

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example, Balch et al. teach that all of the components of a sample are moved into the separation material present in the microchannels.

Accordingly, for at least the reason described above, Balch et al. do not anticipate Claims 1-16 and the claims that depend therefrom. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 1-16 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Nelson et al. (US 5,746,901). The Applicants respectfully submit that Nelson et al. do not anticipate Claims 1-16 as Nelson et al. do not teach each and every claimed limitation.

As described above, Claims 1-16 specify methods wherein a multi-component fluidic sample is contacted with a micro-valve under conditions for at least one component to at least move into the micro-valve while the remaining components remain outside the micro-valve.

Nelson et al. do not teach such a method. Rather, Nelson et al. teach a device with an enrichment medium present in an enrichment channel. In the invention of Nelson et al., a sample is moved through the enrichment medium to a main flowpath and waste from the enrichment channel is diverted from the main flowpath via a discharge outlet (see for example col. 3, lines 17-25). However, Nelson et al. do not teach a method wherein at least one component of a multi-component fluid sample is at least moved into a micro-valve while other component of the fluid sample remain outside the micro-valve or rather do not move into the micro-valve at all. For example, Nelson et al. teach that all of the components of a sample are moved into an enrichment channel. In other words, in regards to the enrichment channel, Nelson does not teach that there are components of the sample that remain outside the enrichment channel as Nelson et al. teach that all of the sample components are moved into the enrichment channel.

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For example, in describing the enrichment channels, Nelson et al. teach the following:

The enrichment channel thus serves to selectively retain and separate the target analyte comprising fraction from the remaining components or the waste portion of the initial sample volume.  
Col. 3, lines 63-67.

In embodiments where the enrichment means is a chromatographic material, typically sample will be introduced into, and allowed to flow through, the enrichment channel. As the sample flows through the enrichment channel, the analyte comprising fraction will be retained in the enrichment channel by the chromatographic material and the remaining waste portion of the sample will flow out of the channel through the waste outlet...An elution liquid will then be caused to flow through the chromatographic material to release the enriched sample fraction from the material and carry it to the main electrophoretic flowpath.  
Col. 5, lines 15-36. (Emphasis added.)

Accordingly, Nelson et al. do not teach a method employing a micro-valve having a phase reversible material wherein at least one component of a sample contacted with the micro-valve is at least moved into the micro-valve and the remaining components of the sample remain outside the micro-valve.

For at least the reasons described above, Nelson et al. do not anticipate Claims 1-16 and the claims that depend therefrom. As such, the Applicants respectfully request that this rejection be withdrawn.

**REJECTION UNDER 35 U.S.C. §103**

Claims 17-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Balch et al. or Nelson et al. The Applicant respectfully submits that Claims 17-20 are patentable under 35 U.S. C. §103(a) over Balch et al. and Nelson et al.

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The M.P.E.P. provides clear guidance on the requirements of a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

M.P.E.P. § 2142. (Emphasis added.)

Thus, the cited reference must teach or suggest all of the limitations of the claimed invention for the claimed invention to be rendered obvious over the reference.

Independent Claim 17, and claims 18-20 that depend therefrom, recite a kit that includes (1) a micro-fluidic device having a fluid flow path and at least one micro-valve that includes a phase reversible material, and (2) at least one of: instructions for practicing the method of Claim 1 or means for obtaining instructions for practicing the method of Claim 1. Accordingly, a component of the claimed kits is directed towards instructions for practicing the method of Claim 1 or means for obtaining such instructions. As such, in order to render obvious Claims 17-20, a reference or combination of references must teach or suggest at least one of: instructions for practicing the method of Claim 1 or means for obtaining instructions for practicing the method of Claim 1.

As described above, neither Balch et al. nor Nelson et al. teach all of the claimed limitations of Claim 1, e.g., neither of these references teaches a method that includes contacting a multi-component fluidic sample with a micro-valve

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under conditions for at least one component of the fluid sample to at least move into the micro-valve while the remaining components remain outside the micro-valve. Consequently, neither of these references teaches a kit that includes instructions for practicing the method of Claim 1 or means for obtaining instructions for practicing the method of Claim 1 as neither teaches such a method.

Furthermore, as neither Balch et al. nor Nelson et al. teach the method of Claim 1, neither of these references even suggests all of the claimed limitations of Claim 1, e.g., neither of these references suggests a method that includes contacting a multi-component fluidic sample with a micro-valve under conditions for at least one component of the fluid sample to at least move into the micro-valve while the remaining components remain outside the micro-valve. Consequently, neither of these references suggests a kit that includes instructions for practicing the method of Claim 1 or means for obtaining instructions for practicing the method of Claim 1 as neither reference suggests such a method.

Specifically, in reference to the use of the hybrid electrophoresis system of Balch et al., Balch et al. teach that "Biomolecules are loaded into the microchannels...and are separated as they migrate down the microchannels by the microslab positioned to cover the microchannels." (col. 4, lines 18-24). Nowhere is it explicitly taught or even suggested that a multi-component fluidic sample is contacted with a micro-valve under conditions for at least one component of the fluid sample to at least move into the micro-valve while the remaining components remain outside the micro-valve as Balch et al. explicitly describe the migration of all of the contacted biomolecules down the microchannels, i.e., none remain outside the microchannels. Accordingly, Balch et al. do not even suggest the method as claimed in Claim 1 and thus do not suggest a kit that includes instructions for practicing the method of Claim 1 or means for obtaining instructions for practicing the method of Claim 1 as Balch et al. do not suggest such a method.

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In regards to Nelson et al., Nelson et al., teach that the enrichment channel serves to selectively retain and separate the target analyte comprising fraction from the remaining components or the waste portion of the initial sample volume. (col. 3, lines 63-66) Nowhere is it explicitly taught or even suggested that a multi-component fluidic sample is contacted with a micro-valve under conditions for at least one component of the fluid sample to at least move into the micro-valve while the remaining components remain outside the micro-valve as Nelson et al. teach the selective retention and separation of components of sample. In other words, Nelson et al. teach that all of the sample components enter an enrichment channel for retention and separation. Accordingly, Nelson et al. do not even suggest the method as claimed in Claim 1 wherein some of the sample components remain outside a micro-valve and thus do not suggest a kit that includes instructions for practicing the method of Claim 1 or means for obtaining instructions for practicing the method of Claim 1 as Nelson et al. do not suggest such a method.

For at least the reasons described above, Claims 17-20 are patentable over Balch et al. and Nelson et al. As such, the Applicants respectfully request that this rejection be withdrawn.



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### CONCLUSION

The applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at (650) 327-3400.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078.

Respectfully submitted,

Date: 8/18/03

By: [Signature]  
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